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10/800,339	03/12/2004	James W. Voegele	END5241USNP	9931

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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/800,339	VOEGELE, JAMES W.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7 and 21-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7 and 21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 1/29/2010. Claims 1 and 21 are amended. Claim 34 is cancelled. **Claims 1, 5, 7, and 21-33** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (US Pat No. 6471700) in view of Wardle et al (US Pub No. 20020120211), further in view of Truckai et al (US Pat No. 6485436).

4. In regards to **Claim 1**, Burbank et al discloses a biopsy device comprising:

a tissue piercing element 24, 190 having a conductive tip electrode 28, 192, best seen in Figure 1 and 12 respectively;

a hollow sleeve 12 adapted to fit over and receive the tissue piercing element therein, best seen in Figure 3 and 13, the sleeve comprising an open proximal end, a distal end 18, a sidewall extending between the proximal end and the distal end, and a tissue receiving opening 16 disposed intermediate the proximal end and the distal end, wherein the tissue receiving opening is formed laterally in the sidewall, best seen in Figure 1, and the sleeve comprising a connector

20 for releasably attaching the sleeve to a biopsy device 24, 190 comprising the tissue piercing element, best seen in Figure 3 and 13 (Col.6: 10-34);

wherein the tip electrode is disposed distal of the distal end of the hollow sleeve when the tissue piercing element is received in the hollow sleeve, and wherein the tip electrode extends through the distal end of the sleeve when the tissue piercing element is received in the hollow sleeve, best seen in Figure 3 and 13.

5. However, Burbank et al do not disclose at least two electrodes disposed on the sleeve. It is however noted that Burbank et al teach the use of electrocautery unit 150 in conjunction with hollow sleeve 12 to effectively provide coagulation, i.e. cauterize the region where samples are taken to stop bleeding and reduce the probability of infection, best seen in Figure 15 (Col.12: 30-39).

6. Wardle et al teach an analogous hollow sleeve 14 with at least two electrodes 20 disposed on the sleeve, the at least two electrodes capable of and thus adapted to provide coagulation, best seen in Figure 2B (left and right) (¶0030). Truckai et al disclose an analogous device comprising an electrode 196 disposed on an outer sleeve 110A such that at least a portion of the electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7, to effectively cauterize the biopsy area (Col.6: 50-63).

7. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hollow sleeve of Burbank et al to have at least two electrodes disposed in the manner described above on the sleeve and are adapted for providing coagulation as taught by Wardle et al and Truckai et al respectively, to predictably provide a more integral

device wherein the hollow sleeve advantageously provides electrodes for cauterization of the biopsy site after a sample is taken, wherein in combination, the tip electrode is spaced axially from the at least two electrodes disposed on the sleeve when the tissue piercing element is received in the hollow sleeve.

8. In regards to **Claim 5**, Wardle et al and Truckai et al disclose first and second electrodes associated with the edges of the tissue receiving opening, best seen in Figure 1 of Wardle et al and Figure 7 of Truckai et al.

9. **Claims 21-25, and 27-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck (US Pat No. 6740082), further in view of Truckai et al.

10. In regards to **Claim 21**, Wardle et al disclose a biopsy device comprising:

a hollow sleeve (14) comprising a proximal end, a distal end, a unitary sidewall extending from the distal end to the proximal end, best seen in Figure 2B, and a lateral opening (22, 26) formed through a portion the unitary sidewall, wherein the lateral opening is configured to receive tissue, wherein the sleeve is configured to axially receive a portion of a biopsy probe instrument (44), and the sleeve comprising a connector for releasably attaching the sleeve to the biopsy probe instrument best seen in Figure 4, wherein the connector is defined as the end portion of the sleeve by thumbwheel 32 at which point said biopsy probe instrument is insertedly attached to the sleeve, also shown in Figure 1;

at least one electrode (20) disposed on an outer surface of the sleeve, best seen in Figure

2B;

a conductive tip electrode (72) slidably received within the hollow sleeve (¶0040), best seen in Figure 1.

11. However, Wardle et al do not disclose said at least one electrode disposed proximally of a distal most portion of the lateral opening. Shadduck discloses an analogous sleeve comprising electrodes (45a-b) disposed proximally of a distal most portion of a lateral opening (76), as an effective configuration for the desired tissue contact, best seen in Figure 6B. Truckai et al disclose two electrodes 196 (paired bi-polar electrodes, Col.6: 61) disposed on an outer surface of sleeve 110A, wherein the two electrodes each extend circumferentially about opposed portions of the circumference of the sleeve, best seen in Figure 7 (Col.6: 50-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the positioning of the electrode of Wardle et al such that said electrode is disposed proximally of a distal most portion of the lateral opening, as taught by Shadduck and to have the electrodes circumferentially opposed on the sleeve as taught by Truckai et al, to produce an effective electrode configuration that enhances tissue contact to achieve the predictable result of proper tissue biopsy.

12. In regards to **Claim 22**, Wardle et al disclose the lateral opening (22) is located proximal of the distal end of the sleeve, wherein a portion of the sleeve separates the lateral opening from the distal end of the sleeve, best seen in Figure 2B.

13. In regards to **Claim 23**, Wardle et al disclose a portion of the sidewall extends unitarily

from the proximal end of the sleeve to the distal end of the sleeve, best seen in Figure 2B.

14. In regards to **Claim 24**, Wardle et al disclose a connector operable to selectively couple the sleeve with the biopsy probe instrument, best seen in Figure 4.

15. In regards to **Claim 25**, Wardle et al disclose the sleeve (14) has an open distal end (22, 26), which is an opening at the distal end, wherein the sleeve is configured to axially receive a biopsy probe (44) having a distal tip (72) for penetrating tissue, and wherein the sleeve is configured such that the distal tip of a biopsy probe extends distally from the open distal end of the sleeve when the sleeve is disposed axially over the biopsy probe, best seen in Figures 2-3.

16. In regards to **Claim 27**, Wardle et al disclose the biopsy probe instrument is configured to communicate electrical signals to the electrodes (20) when the sleeve (14) is coupled with the biopsy probe instrument (¶0034-0035).

17. In regards to **Claim 28**, Wardle et al disclose the electrodes (20) are configured and capable to receive communication of electrical signals for a power source independent of the biopsy probe instrument.

18. In regards to **Claim 29**, Wardle et al in combination with Shadduck disclose first and second electrodes positioned along opposites of the lateral opening (22, 26), wherein such variable positioning is obvious to one of ordinary skill in the art, such as that shown in Shadduck Figure 6A.

19. In regards to **Claim 30**, Wardle et al in combination with Shadduck disclose the one or more electrodes comprises an annular electrode positioned at the distal end of the sleeve (14).

20. In regards to **Claim 31**, Wardle et al in combination with Shadduck disclose the one or

more electrodes comprises a pair of electrodes separated by an electrode gap, best seen in Figure 6B (Shadduck).

21. In regards to **Claim 32**, Wardle et al disclose the distal end of the sleeve (14) is open (22, 26), wherein there is an opening at the distal end of the sleeve, best seen in Figure 2B.

22. In regards to **Claim 33**, Wardle et al in combination with Shadduck disclose two electrodes, each electrode extending lengthwise in a direction parallel to the longitudinal axis of the sleeve, and at least a portion of each electrode disposed proximally of a distal most portion of the lateral opening, best seen in Figure 6B (Shadduck).

23. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al ('700), Wardle et al, and Truckai et al in view of Burbank et al (US Pat No. 6540695) and Russell et al (US Pat No. 6500144).

24. Burbank et al ('700) in combination with Wardle et al and Truckai et al as modified in the manner above disclose at least two electrodes disposed on an outer surface of the sleeve but are silent as to the dimensions of the electrodes (20). Burbank et al teach electrodes (18), best seen in Figure 1, with a width dimension of between about 3 mm and about 8 mm (Col.11: 58-67). Russell et al teach electrodes (20), best seen in Figure 1, with a length dimension of between about 20 mm and about 40 mm (Col.7: 4-15) as effective sizes for the desired tissue application within the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the at least two electrodes of Burbank et al ('700) as modified by Wardle et al and Truckai et al with a width of about 3mm – 8 mm and a length of

about 20 mm – 40 mm, as taught by Burbank et al ('695) and Russell et al respectively, to dimension the electrodes at an appropriate size for the desired tissue application.

25. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck and Truckai et al, further in view of Burbank et al (US Pat No. 5526822).

26. Wardle et al in combination with Shadduck and Truckai et al disclose the sleeve (14) with a lateral opening (22, 26) for tissue communication and a biopsy probe instrument (44) but do not disclose said biopsy probe instrument with a tissue receiving window. Burbank et al disclose an analogous biopsy probe instrument (468) with a tissue receiving window (476) disposed within an analogous sleeve (444) also with a lateral opening (446), best seen in Figure 14A, wherein when the sleeve is coupled with the biopsy probe instrument, the sleeve is configured such that the lateral opening permits communication of tissue through the lateral opening of the sleeve and through the tissue receiving window of the biopsy probe instrument (Col.18: 53-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy probe instrument of Wardle et al as modified by Shadduck and Truckai et al to include a tissue receiving window, as taught by Burbank et al, such that when said biopsy probe instrument is coupled to the sleeve the lateral opening of the sleeve enables communication of tissue through the lateral opening and through the tissue receiving port to ensure the prolapse and subsequent effective capture of the tissue.

Response to Arguments

27. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection. It is noted that applicant has not provided any specific arguments against the above references teaching the newly amended limitations, nor against the previous rejection.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736